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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,628	02/23/2004	Joseph P. Errico	F-272	8401
51640	7590	01/24/2008	EXAMINER	
SPINE MP			CUMBERLEDGE, JERRY L	
LERNER, DAVID, et al.			ART UNIT	PAPER NUMBER
600 SOUTH AVENUE WEST				3733
WESTFIELD, NJ 07090				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/784,628	ERRICO ET AL. <i>CT</i>
	Examiner	Art Unit
	Jerry Cumberledge	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 November 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-20 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1-20 are objected to because of the following informalities:

There exists an inconsistency between the language of claim 1 and that of the claim 2 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, lines 1-2, applicant recites "An apparatus" with the orthopedic device being only functionally recited, i.e. "for manipulating an orthopedic device", thus indicating that the claim is directed to the subcombination, "An apparatus". However, in claim 2, lines 1-3, applicant further narrows the scope of the orthopedic device (i.e. "...wherein the device is one of an artificial disc, a static trial, and a distraction spacer"), thus indicating that the combination, an apparatus and an orthopedic device is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination.

Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-11 will be considered as being drawn to the subcombination, an apparatus.

Claim 12 and 19 are objected to for the same reasoning.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-15, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kountz (US Pat 1,518,205).

Kountz discloses an apparatus for manipulating an orthopedic device having first and second baseplates, the first baseplate having a first vertebral body contacting surface and the second baseplate having a second vertebral body contacting surface, the apparatus comprising: at least one shaft (Fig. 2, ref. 10) having a longitudinal axis (Fig. 2) and a shaft distal end (Fig. 2, near ref. 20) adapted for engagement with the orthopedic device (Fig. 2), the shaft distal end further having forward surfaces (Fig. 2, surfaces near ref. 21) for engagement with corresponding confronting surfaces of at least one of the baseplates for axial rotationally aligning the at least one of the baseplates with respect to the longitudinal axis in at least two of a plurality of possible axial rotationally aligned positions (Fig. 2), wherein each of such possible axial rotationally aligned positions aligns the longitudinal axis of the shaft with respect to a respective one of the corresponding confronting surfaces (Fig. 2). The device is one of an artificial intervertebral disc, a static trial, and a distraction spacer. The forward surfaces of the shaft distal end are flat and angled with respect to one another for mating with the confronting surfaces of the baseplates (Fig. 2, near corners), the confronting surfaces being correspondingly flat and angled. The forward surfaces are angled with respect to one another at an orientation angle that facilitates engagement of the apparatus with the device in a plurality of rotated positions with respect to the device

such that possible engagement orientations approaches include at least an anterior insertion approach and at least one anterior-lateral insertion approach (Fig. 2). The forward surfaces are adapted for engagement with the device such that either an anterior-laterally facing forward surface and an anteriorly facing forward surface is mateable with any of an anterior-laterally facing confronting surface and an anteriorly facing confronting surface (Fig. 2). The anteriorly facing forward surface is spaced from the anteriorly facing confronting surface when two anterior-laterally facing surfaces are engaged with two anterior-laterally facing forward surfaces (Fig. 2). The anteriorly facing forward surface has a length greater than the anteriorly facing confronting surface (Fig. 2). Engagement of at least two of the forward surfaces with at least two of the confronting surfaces significantly limits movement of the at least one of the baseplates relative to the apparatus (Fig. 2). Engagement of at least two of the forward surfaces with at least two of the confronting surfaces substantially minimizes rotation of either of the baseplates about a longitudinal axis of the device (Fig. 2). The apparatus further comprising at least one vertebral body stop (Fig. 2, ref. 19), wherein the stop prevents over-insertion of the device into an intervertebral space (Fig. 2).

Kountz discloses an apparatus for holding an orthopedic device the orthopedic device including a first baseplate having a first vertebral body contacting surface and a second baseplate having a second vertebral body contacting surface, the apparatus comprising: a shaft (Fig. 2, ref. 10) having a distal end (Fig. 2, near ref. 20) and a longitudinal axis (Fig. 2); an extendible and retractable holding pin (Fig. 2, ref. 34) located internal to at least a portion of the shaft distal end (Fig. 2); and a spring (Fig. 2,

ref. 31) coupled to the holding pin (Fig. 2) and located internal to at least a portion of the shaft (Fig. 2) and biasing the pin toward retraction along a direction parallel to the longitudinal axis of the shaft (Fig. 2); wherein a holding pin distal end of the holding pin is bent downwardly (Fig. 2, near ref. 35) such that the holding pin distal end prevents the holding pin from being entirely retracted within the shaft under the bias (Fig. 2); wherein the holding pin engages and disengages a corresponding holding pin device hole of the device (Fig. 2); wherein the spring spring-loads the holding pin toward at least one shaft distal end surface of the shaft distal end (Fig. 2) such that when the holding pin is engaged with the corresponding holding pin device hole, the spring spring-loads at least one surface of the device to at least one of the shaft distal end surfaces (Fig. 2). The holding pin extends through the shaft distal end in a direction along a longitudinal axis of the shaft (Fig. 2). The device comprises the first baseplate and the second baseplate, and wherein the holding pin engages and disengages a corresponding holding pin baseplate hole of at least one of the baseplates. The apparatus further comprising a flange (Fig. 2, portion near where ref. 33 is attached) mechanically coupled to the holding pin, wherein exerting pressure on the flange in a distal direction overcomes the bias of the spring to space the holding pin at a distance from the shaft distal end (Fig. 2).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Kountz which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kountz (US Pat 1,518,205).

Kountz discloses the claimed invention except for the forward surfaces being angled with respect to one another at an orientation angle of approximately 33.4 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the device forward surfaces at an orientation angle of approximately 33.4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kountz (US Pat 1,518,205) in view of Hilterhaus (US Pat. 3,743,042).

Kountz discloses the claimed invention except for the apparatus further comprising a knob coupled to the shaft, wherein rotation of the knob moves the flange such that the holding pin moves closer to the shaft distal end, and wherein reverse rotation of the knob moves the flange such that the holding pin moves away from the shaft distal end. The knob is threaded to the shaft. Interference between threads of the knob and threads of the shaft lock the holding pin in position. The orthopedic device is selected from the group consisting of an artificial intervertebral disc, a static trial, and a distraction spacer. The first and second baseplates of the orthopedic device are joined by a central coupling that enables the first and second baseplates to rotate and angulate relative to one another.

Hilterhaus discloses an apparatus (Fig. 2) that comprises a shaft (Fig. 2, ref. 11), a spring (Fig. 2, ref. 24), and pin (Fig. 2, ref. 29) with a bent portion (Fig. 2, ref. 30) and a knob with a threaded connection (column 1, lines 45-64). This helps to seal the device and connect the components of the device together (column 1, lines 45-64).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Kountz with a knob as taught by Hilterhaus, in order to help seal the device and to connect the components of the device together (column 1, lines 45-64).

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JERRY CUMBERLEDGE
EDUARDO ROBERT
CUMBERLEDGE & ROBERT, PLLC